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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,990	10/22/2001	Peter David Davis	U 013588-9	1813

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26 WEST 61ST STREET
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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/05/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,990

Applicant(s)

Davis, P.D.

Examiner

CHARANJIT AULAKH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep. 15, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

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DETAILED ACTION

1. According to paper no. 12 filed on Sep. 15, 2003, the applicants have canceled claims 1-20 and furthermore, have added new claims 21-40. The applicants have also submitted a new abstract.
2. Claims 21-40 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inducing necrosis using inhibitor of nitric oxide synthase selected from the group consisting of -C(O)CH(NH₂)-(CH₂)_p-NHC(NH)Z- and -NHCH(CO₂R₁₀)-(CH₂)_p-NHC(NH)Z-, does not reasonably provide enablement for all known as well as to be developed inhibitors of nitric oxide synthase or formation of nitric acid (see claim 21). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

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Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art.

There are three different forms of NO synthase (NOS) such as nNOS, iNOS and eNOS with different localization and different function as reported in the prior art by Chinje et al. (Essays in biochem. , cited on applicants form 1449). However, there is no teaching in the specification that inhibitors of all three forms of NOS will enhance the efficacy of CA4p. The specification teaches higher necrosis using exemplified compounds 1 and 2 (see page 15) compared to CA4p alone. The specification also does not teach which form of NOS is critical for enhancing efficacy of CA4p in inducing necrosis. There is no teaching either in the specification or prior art that all known NOS inhibitors inhibit either all three forms of NOS or a specific form of NOS since their localization and function is different as mentioned above. There is no teaching or guidance in the specification that inhibitors of all three forms of NOS will have same utility in enhancing the efficacy of CA4p. In absence of such teachings and guidance, it would require undue experimentation to demonstrate the effectiveness of all known as well as to be developed in the future NOS inhibitors in enhancing efficacy of CA4p in inducing necrosis.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 21-35 provide for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 22-40 depend directly or indirectly upon claim 21. In claim 21, the second moiety is listed as inhibitor of the formation or action of nitric acid. Is it true? According to the specification, it should be ---nitric oxide---. An appropriate correction is required.

In claim 21, it is not clear how the two moieties are coupled. The applicants are suggested to include the formula showing attachment of two moieties.

Claim 23 recites the limitation "hydrate, salt or prodrug" in claim 21. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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8. Claims 21-35 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on "Monday-Thursday" from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.


CHARANJIT S. AULAKH

PRIMARY EXAMINER